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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,592	08/15/2005	Morten Sloth Weidner	030307-0249	1815

22428 7590 09/09/2010
FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
KAROL, JODY LYNN	

ART UNIT	PAPER NUMBER
1627	

MAIL DATE	DELIVERY MODE
09/09/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,592	WEIDNER, MORTEN SLOTH	
	Examiner	Art Unit	
	Jody L. Karol	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/8/2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64,72-76 and 94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64,72-76 and 94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/8/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 7/8/2010. Claims 64, 73, 75, and 94 have been amended. Claims 1-63, 65-71, 77-93, and 95-96 are cancelled. Claims 64, 72-76, and 94 are pending and are currently under consideration.

Information Disclosure Statement

1. The information disclosure statement (IDS) filed on 7/8/2010 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered.

WITHDRAWN REJECTIONS

2. In view of Applicant's amendment to claim 94, the rejection of claim 94 under 35 U.S.C. 112, 2nd paragraph, as being indefinite, is herein withdrawn.

MAINTAINED REJECTIONS

3. The following rejections have been maintained from the previous Office Action dated 1/12/2010, but have been slightly modified to account for Applicant's amendments to claims 64 and 94:

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 64, 72-76, and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crook et al. (WO 00/71093 A1) in view of Cornwell et al. ("Glyceryl monocaprylate/caprate as a moderate skin penetration enhancer," *International Journal of Pharmaceutics*, 171 (1998); pgs 243-255).

The instant claims are directed to compositions for the treatment of dermal inflammation comprising a combination of (i) glyceryl monocaprylate or an alkali metal salt thereof and (ii) niacinamide or salt thereof, wherein the ratio of (i) to (ii) are present in a molar ratio of between about 1:3 and 1:16.

Crook et al. teach topical, leave on skin care composition comprising from 1% to 10% of a vitamin B_3 compound and a high spreading oil in a dermatologically

acceptable carrier, wherein the compositions are preferably emulsions (see abstract). The vitamin B_3 is preferably niacinamide (see page 4, lines 5-9; page 5, lines 1-2). Crook et al. further teach emollients that may be present in the composition include monoglycerides of C_1-C_{30} carboxylic acids, and surfactants include polyglyceryl esters of C_1-C_{30} fatty acids (see page 13, lines 27-28). Crook et al. also teach skin penetration enhancers may be present in the composition, as well as other active agents such as anti-acne agents, organic hydroxy acids, etc. as claimed in the instant claim 74 (see page 9, lines 18-31).

Crook et al. do not exemplify glyceryl monocaprylate as present in the compositions comprising niacinamide, or the molar ratio of glyceryl monocaprylate to niacinamide as claimed in the instant claims 64 and 94.

Cornwell et al. teach glyceryl monocaprylate/caprate had skin penetration enhancement effects significantly above the buffer control in increasing the penetration of 5-fluorouracil (a hydrophilic drug) in a comparison of lipophilic formulation excipients screen for their skin penetrating effects (see abstract). Cornwell et al. also teach that glyceryl monocaprylate/caprate has surfactants properties, and the optimum alkyl chain length for surfactant-type skin penetration enhancers (see abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the glyceryl monocaprylate/caprate as the penetration enhancer in the composition comprising niacinamide taught by Crook et al. One of ordinary skill in the art would have been motivated to use glyceryl monocaprylate/caprate as the penetration enhancer in the composition comprising niacinamide because penetration

enhancers are optional components in the compositions taught by Crook et al. One of ordinary skill in the art would have had a reasonable expectation of success in using glyceryl monocaprylate/caprate as the penetration enhancer in the composition comprising niacinamide because Cornwell et al. teach glyceryl monocaprylate/caprate enhanced the penetration of a hydrophilic drug, 5-fluorouracil, and niacinamide is hydrophilic drug. Further, it is noted that composition taught by Crook et al. may include monoglycerides of C_1-C_{30} carboxylic acids and polyglyceryl esters of C_1-C_{30} fatty acids may be present as emollients and surfactants respectively, wherein glyceryl monocaprylate/caprate is a species of said esters, and as taught by Cornwell et al., a surfactant.

While the prior art references do not explicitly teach the claimed molar ratio of glyceryl monocaprylate to niacinamide as claimed in the instant claims 64 and 94, the determination of optimal or workable ratio molar ratio of glyceryl monocaprylate to niacinamide by routine experimentation is obvious absent showing of criticality of the claimed amount. One having ordinary skill in the art would have been motivated to do this to obtain the desired penetration enhancing effects of the niacinamide composition.

It is noted that the recitation "for the treatment of dermal inflammation" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190

USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art.

Response to Arguments

6. Applicant's arguments filed 7/8/2010 have been fully considered but they are not persuasive.

Applicant argues the claims have been amended to recite specific ratios of niacinamide with glyceryl monocaprylate not taught or suggested by the prior art references. In response it is respectfully submitted that the determination of optimal or workable ratio molar ratio of glyceryl monocaprylate to niacinamide by routine experimentation is obvious absent showing of criticality of the claimed amount. One having ordinary skill in the art would have been motivated to do this to obtain the desired penetration enhancing effects of the niacinamide composition.

Applicant further argues that the claims have been amended to recite the intended use of the composition as a composition for the treatment of dermal inflammation. In response it is respectfully submitted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicant alleges that the claimed compositions have unexpected results in regards to the treatment inflammation and that said results are commensurate with the scope of the claims by at least two measures: (1) intended use of the composition and (2) composition of the composition (i.e. the molar ratios of 2:7 and 1:14 in claim 94). In response it is respectfully submitted that it is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

In the instant case, the evidence of alleged synergism is not commensurate with the breadth of the claims. Only two specific formulations are provided as evidence: 1-glyceryl monocaprylate and nicotinamide in a molar ratio of 1:14 and in a molar ratio of 2:7 (see Examples 111 and 112). It is noted that while Example 111 compares the composition containing glyceryl monocaprylate and nicotinamide in a molar ratio of 1:14 with the individual components to demonstrate synergism, Example 112 does not compare the composition containing glyceryl monocaprylate and nicotinamide in a molar ratio of 2:7 to its individual components. Thus, it remains unseen if the composition containing glyceryl monocaprylate and nicotinamide in a molar ratio of 2:7

contains any synergistic effects between the components. The single data point demonstrating a synergistic effect between glyceryl monocaprylate and nicotinamide (i.e. a molar ratio of 1:14) does not provide sufficient efficient evidence that the remaining composition formulations containing different molar ratios and concentrations would exhibit the same or similar unexpected results. It is noted that the claim 64 specifies a fairly broad molar ratio of 1:3 to 1:16, and claim 94 encompasses a molar ratio of 2:7 which has not been demonstrated to have a synergistic effect. Therefore, no clear and convincing unexpected benefit is seen to be present herein. Thus, the instant claims are still considered properly rejected under 35 USC 103(a).

Applicant's arguments that 1:3 to 1:16 is commensurate with the exemplified ratios of 1:14 and 2:7 have been fully considered but are not considered persuasive because the ratio of 2:7 has not been demonstrated to have a synergistic effect.

Thus, for these reasons, Applicant's arguments are found unpersuasive. Said rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1627

/Yong S. Chong/
Primary Examiner, Art Unit 1627